UNIVERSITY of ROCHESTER

Research Study Site File Documentation Requirements

The items listed in **TABLE 1** MUST be maintained at the site by the Study Team for any IRB-approved study.
The regulatory file may be stored electronically or in paper form.
Maintaining department-specific items in a central file is acceptable (best practice is to add a Note to File to study documentation indicating where central files are located).

TABLE 1	**Present**		
Regulatory File:	**YES**	**NO**	**NA**
IRB-approved **Protocol**: current version			
IRB-approved **Protocols**: previous version(s)			
Protocol Investigator Signature Page(s) (signed, dated), if applicable			
IRB-approved **Informed Consent Forms**, current watermarked			
IRB-approved **Informed Consent Forms**, previously watermarked			
Initial IRB **Approval Letter**			
IRB **modification approval letters** and associated approved documents			
IRB **re-approval letters** (Continuing Review, as applicable)			
Data and Safety Management Plan/Board documentation and applicable reports as defined by the approved protocol. Note: Documentation to indicate that the Data and Safety Monitoring Plan (DSMP) met protocol-specified expectations is required.			
Documentation to support items as defined by the approved protocol.			
Ancillary committee approvals (i.e., Data Security form, Clinical Research Center, Institutional Biosafety, Radiation Safety)			
Reportable New Information submissions and other IRB communication			
Conflict of Interest Management Plans, as applicable, should be maintained, but do not need to be in the study-specific regulatory file			
Subject-Specific Research Files:	**YES**	**NO**	**NA**
Signed, original **Informed Consent form**(s) NOTE: The person obtaining consent must be an IRB-approved and Human Subject trained study staff member.			
Data Collection sheets/files/source documents/**Case Report Forms**, labeled with study name/number, date collected, and subject identifiers; signed, dated, and completed			
Adverse Event assessment documentation (especially if a greater than minimal risk study)			
Serious Adverse Event assessment document and notification by the Investigator to Sponsor			

Good Documentation Practice reminders include:

- Documentation of Inclusion/Exclusion criteria assessment and Investigator(s) confirmation of eligibility
- Delegation of Authority Log, Signature Log, and other tools may be used for any study, but must be maintained
- Cross-outs must be one-lined through, initialed, and dated.
- Study staff training documentation, especially for significant modifications to the protocol

Good Clinical Practice Research Study Files:
In addition to all listed in **TABLE 1**, the following items in **TABLE 2** are mandatory for investigational drug, device, and/or biologic trials. The on-site research files must have the items listed above *plus* the following, as applicable. Templates for many of these items can be found here.

TABLE 2	**Present**		
Good Clinical Practice Research Study Files:	**YES**	**NO**	**NA**
Principal Investigator, Co-Investigator(s), Sub-Investigator(s) **Curriculum Vitae**			
Principal Investigator, Co-Investigator(s), Sub-Investigator(s) **Professional Licenses/ Certifications**, as applicable			
Delegation of Authority Log			
Staff Signature Log Note: Delegation of Authority and Signature Logs may be combined.			
Subject Screening and Enrollment Log (including all subjects screened, enrolled, screen-failed, withdrawn, lost to follow up, and completed) Note: The Log must correlate the assigned subject identification number with the subject's full name. Only anonymous data can be collected on those who may have been screened but did not provide consent.			
Subject Identification Code List, as applicable			
Randomization Log, as applicable			
Clinical Research Associate/**Monitoring follow-up letters**, as applicable			
If the study is obtaining **Laboratory** samples (i.e., blood specimens): • Laboratory certifications • Laboratory licenses • Normal value laboratory ranges (Laboratory ranges may be accessed here: http://www.urmc.rochester.edu/urmc-labs.aspx) • Record of Retained Body Fluids/Tissue Samples (if applicable)			
Investigational Product (IP)/Device accountability information: • Subject-specific, including assignment and dispensing • Sample of IP label or device • Dispensing Log (tracking information, expiration dates, shipping, proper storage, destruction) • Temperature Log (for IP storage location) • Investigator's Brochure, device information, product insert, as applicable			
FDA 1572, as applicable			
FDA 3455 Financial Disclosure form, as applicable.			
FDA 1571, as applicable			
Relevant **Communications**			